premised upon the Examiner's oral agreement that the prior art rejection was overcome, which Applicants expected would be part of the record.

Remarks in Response to the §112 Rejection:

This rejection is based on the Examiner's holding sequentially the opinions that the term "alpha-starch" is not adequately defined in the art and is a trade name.

With respect to the Examiner's latter assertion, first articulated in the Advisory Action of November 22, 2002, Applicants respectfully respond that the designation "alpha-starch" is generic and is not a trade name. It designates a modified (pregelatinized) starch. In support of this position, Applicants submitted excerpts from some U.S. patents copied from electronic copies of these patents found in the USPTO database.

As made of record in the response to an Office Action dated March 17, 2002, Applicants had conducted a search, pointing to the use of the term "alpha-starch" in 173 U.S. patents, the first 50 of which had then been specifically identified to the Examiner (See **Attachment A**). The search strategy and total results are also reflected in Attachment A.

The Examiner had considered this evidence but found it unpersuasive, stating that it is not a dictionary definition and that it appears to be a term known only in the Japanese language (see August 28, 2002, Office Action at page 2, paragraph 1).

Thus, prior to the February 25, 2003 interview, and prior to the Final Action, Applicants had already pointed out that the 173 patents were U.S. patents issued in the English language. Illustrative of this probative evidence are the following excerpts from among the 173 patents, which indicate that "alpha-starch" is a starch derivative, distinguishable from other

starch material and other binders. This evidence was clearly timely before the Examiner and considered by the Examiner.

U.S. Patent No. 6,227,869 (#34 in Attachment A) includes the term "alpha-starch."

> Examples of this polymer compound having a sugar skeleton are starch such as **.alpha.-starch**, .beta.-starch, corn starch, potato starch, and dogtooth violet starch; grain powders containing starch as its main component such as wheat flour, barley flour, rye flour, and rice flour; starch derivatives such as methylstarch, ethylstarch, acetylstarch, and nitrostarch; cellulose; cellulose derivatives such as cellulose acetate, methylcellulose, ethylcellulose, and nitrocellulose; polysaccharides and their derivatives such as dextrin, dextran, mannan, amylopectin, amylose, xylan, glycogen, inulin, lichenin, chitin, hemicellulose, pectin, vegetable gum, agarose, carrageenin, and saponin.

The specification of U.S. Patent No. 6,392,082 (#4 in Attachment A) includes the term "alpha-starch."

> Examples of suitable excipients includes sugar derivatives such as lactose, sucrose, glucose, mannitol or sorbitol; starch derivatives such as corn starch, potato starch, **.alpha.-starch**, dextrin or carboxymethylstarch; cellulose derivatives such as crystalline cellulose, low-substituted hydroxypropylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose or internally-cross-linked sodium carboxymethylcellulose; gum arabic; dextran; pullulan; silicate derivatives such as light silicic acid anhydride, synthetic aluminum silicate or magnesium aluminate metasilicate; phosphate derivatives such as calcium phosphate; carbonate derivatives such as calcium carbonate; sulfate derivatives such as calcium sulfate; glycols; and colloidal silica.

U.S. Patent No. 6,391,903 (#6 in Attachment A) includes the term "alpha-starch."

> Examples of suitable excipients includes sugar derivatives such as lactose, sucrose, glucose, mannitol or sorbitol; starch derivatives such as corn starch, potato starch, **.alpha.-starch**, dextrin or carboxymethylstarch: cellulose derivatives such as crystalline cellulose, low-substituted hydroxypropylcellulose, hydroxypropylmethlcellulose, carboxymethylcellulose or internally-cross-linked sodium carboxymethylcellulose; gum arabic; dextran; pullulan; silicate derivatives such as light silicic acid anhydride, synthetic aluminum silicate or

magnesium aluminate metasilicate; phosphate derivatives such as calcium phosphate; carbonate derivatives such as calcium carbonate; sulfate derivatives such as calcium sulfate; glycols and colloidal silica.

U.S. Patent No. 6,417,175 (#2 in Attachment A) also includes the term "alpha-starch."

"Though the drug of the present invention may comprise only Compound (I) itself, it is usually prepared by a conventional manner by using a proper amount of pharmaceutically acceptable carriers, diluents and bulking agents, etc. which are selected from exipients (for example, calcium carbonate, kaolin, sodium hydrogen carbonate, lactose, D-mannitol, starch, crystalline cellulose, talc, fine granulated sugar, porous substance, etc.), binders (for example, dextrin, gums, **.alpha.-starch**, gelatine, hydroxypropylcellulose, hydroxy propyl methyl cellulose, pullulan, etc.), thickeners (for example, a natural gum, a cellulose derivative, an acrylic acid derivative, etc.), disintegrators (for example, carboxymethylcellu lose calcium, crosscarmelose sodium, crospovidone, a low-substituted hydroxypropylcellulose, partly pregelatinized starch, etc.), solvents (for example, water for injection, alcohol, propylene glycol, Macrogol, sesame oil, corn oil, etc.), dispersants (for example, Tween 80, HCO60, poly ethylene glycol, carboxymethylcellulose, sodium alginate, etc.), solubilizing agents (for example, polyethylene glycol, propylene glycol, D-mannitol, benzoic acid benzyl, ethanol, tris amino methane, triethanolamine, sodium carbonate, citric acid sodium, etc.), suspending agents (for example, stearyl triethanolamine, sodium lauryl sulfate, benzalkonium chloride, polyvinyllcohol, polyvinylpyrolidone, hydroxymethylcellulose, etc.), soothing agents (for example, benzyl alcohol, etc.), isotonic agents (for example, sodium chloride, glycerin, etc.), buffer agents (for example, phosphoric acid salt, acetic acid salt, carbonic acid salt, citric acid salt, etc.), lubricants (for example, magnesium stearate, calcium stearate, talc, starch, sodium benzoate, etc.), coloring agents (for example, tar pigment, caramel, ferric oxide, titanium oxide, riboflavins, etc.), corrigents (for example, a sweetning agent, a perfume, etc.), stabilizers (for example, sodium sulfite, ascorbic acid, etc.) and preservatives (for example, paraben, sorbic acid, etc.), etc.

The specification of U.S. Patent No. 6,326,332 (#22 in Attachment A) also includes "alpha-starch."

Examples of this polymer compound having a sugar skeleton are starch such as **.alpha.-starch**, .beta.-starch, corn starch, potato starch, and dogtooth violet

starch; grain powders containing starch as its main component such as wheat flour, barley flour, rye flour, and rice flour; starch derivatives such as methylstarch, ethylstarch, acetylstarch, and nitrostarch; cellulose; cellulose derivatives such as cellulose acetate, methylcellulose, ethylcellulose, and nitrocellulose; polysaccharides and their derivatives such as dextrin, dextran, mannan, amylopectin, amylose, xylan, glycogen, inulin, lichenin, chitin, hemicellulose, pectin, vegetable gum, agarose, carrageenin, and saponin.

U.S. Patent 6,288,059 (#32 in Attachment A) also includes the term "alpha-starch."

The administration route of compound (I) of the present invention includes oral administration in the form of tablets, capsules, granules powders or syrups; parenteral administration in the form of injections or suppositories; inhalation sprays, skin patches, etc. These formulations can be prepared by a known method using carriers such as excipients (e.g. organic excipients including sugar derivatives, such as lactose, sucrose, glucose, mannitol or sorbitol; starch derivatives, such as corn starch, potato starch, **.alpha.-starch**, dextrin or carboxymethyl starch; cellulose derivatives, such as crystalline cellulose, low-substituted hydroxypropylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose, calcium carboxymethylcellulose or internally cross-linked carboxymethylcellulose sodium; gum arabic; dextran and pullulan; and inorganic excipients including silicate derivatives, such as light anhydrous silicic acid, synthetic aluminum silicate or magnesium aluminate metasilicate; phosphates, such as calcium phosphate: carbonates, such as calcium carbonate; and sulfates, such as calcium sulfate), lubricants (e.g. stearic acid and metal stearates such as calcium stearate and magnesium stearate; talc; colloidal silica; waxes, such as bee gum and spermaciti; boric acid; adipic acid; sulfates, such as sodium sulfate, glycol; fumaric acid; sodium benzoate; DL-leucine; sodium salts of aliphatic acids; laurylsulfates, such as sodium laurylsulfate and magnesium laurylsulfate; silicic acids, such as anhydrous silicic acid and silicate hydrate; and the starch derivatives described above), binders (e.g. polyvinyl pyrrolidone, macrogol and the same compounds as those of the above excipients), disintegrators (e.g. the same compounds as those of the above excipients and chemically modified starch-celluloses, such as croscarmellose sodium, carboxymethylstarch sodium and cross-linked polyvinylpyrrolidone), stabilizers (e.g. paraoxybenzoates, such as methylparaben and propylparaben; alcohols, such as chlorobutanol, benzyl alcohol and phenethyl alcohol; benzalkonium chloride; phenols, such as phenol and cresol; thimerosal; dehydroacetic acid; and sorbic acid), corrigents (e.g. normally used sweetening agents, sour agents and perfumes) and diluents.

U.S. Patent No. 6,277,869 (#34 in Attachment A) includes the term "alpha-starch."

> Examples of this polymer compound having a sugar skeleton are starch such as **.alpha.-starch**, .beta.-starch, corn starch, potato starch, and dogtooth violet starch; grain powders containing starch as its main component such as wheat flour, barley flour, rye flour, and rice flour; starch derivatives such as methylstarch, ethylstarch, acetylstarch, and nitrostarch; cellulose; cellulose derivatives such as cellulose acetate, methylcellulose, ethylcellulose, and nitrocellulose; polysaccharides and their derivatives such as dextrin, dextran, mannan, amylopectin, amylose, xylan, glycogen, inulin, lichenin, chitin, hemicellulose, pectin, vegetable gum, agarose, carrageenin, and saponin.

The specification of U.S. Patent No. 6,416,503 (#3 in Attachment A) lists the term "alpha-starch."

> In addition to the above additives, film bases that are not necessarily soluble in water or film bases that dissolve within a particular pH range (Pharm Tech Japan, Vol. 7, pp. 51-79, 1991) may be added in appropriate amounts, to control drug release. Such film bases include methyl cellulose, ethyl cellulose, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate, carboxymethyl cellulose sodium, carboxymethylethyl cellulose, cellulose acetate phthalate, hydroxyethyl cellulose, **alpha-starch**, aminoacrylmethacrylate copolymers (Eudragit E, Eudragit RS), methacrylic acid copolymers (Eudragit L, Eudragit S), alginic acid propylene glycol ester (Kimiloid), purified shellac and white shellac, or the like.

The specification of 6,388,077 (#7 in Attachment A) includes the term "alpha-starch."

> Formulation Example 1
> 20.0 grams of compound of Example 1, 417 grams of lactose, 80 grams of crystalline cellulose and 80 grams of partial **.alpha.-starch** were blended with a V-cone blender. To the mixture was added 3.0 grams of magnesium stearate and the whole was blended. The blended powder was compressed into 3000 tablets by conventional procedure so that each tablet has a weight of 150 mg and 7.0 mm in diameter.

The foregoing and following excerpts are represented to be copied from electronic copies of these U.S. patents. They are submitted as evidence, and not as prior art.

Additionally, Applicants have also presented excerpts of additional U.S. patents, not previously specifically identified to the Examiner but also gleaned in the same search, which make clear that "alpha-starch" is a physically modified starch obtained by gelatinizing starch:

U.S. Patent No. 6,515,054, col. 5, lines 54-68 and col. 6, lines 1-9 recites:

> In the present invention, particularly preferable among the above-exemplified fillers are the starches (e.g. starch polymers, natural starch extracted from plants), and specific examples thereof include raw starches (grain starch such as corn starch, potato starch, sweet potato starch, wheat starch, cassava starch, sago starch, tapioca starch, millet starch, rice starch, bean starch, arrowroot starch, bracken starch, lotus starch and water caltrop starch), physically modified starches (e.g. .**alpha.-starch**, fractionated amylose, moistly and thermally treated starch), enzymatically modified starches (e.g. hydrolyzed dextrin, enzymolyzed dextrin, amylose), chemical decomposition-modified starches (e.g. acid-treated starch, hypochlorous acid-oxidized starch, dialdehyde starch), chemically modified starch derivatives (e.g. esterified starch, etherified starch, cationized starch, crosslinked starch), and their mixtures.

U.S. Patent No. 5,972,507 explains at col. 4, lines 39-49 that:

> "Polysaccharides used for the production of porous cellulose beads should be alkali-soluble and be easily hydrolyzable by acids. Such polysaccharides include starch and its derivatives, pullulan, dextran and gum arabic. Starch and its derivatives are especially preferable because they are cheap. They may be of potato, corn or tapioca origin, or may be chemically, physically or biologically modified starch. Such modified starch include such as dextrin, acid-treated starch, oxidized starch and dialdehyde starch, starch ethers such as carboxymethylated starch and hydroxyethylated starch, starch esters such as monostarch phosphate and acetylated starch, physically modified starch such as **alpha-starch** and heat-moisture treated starch, and enzyme-treated starch such as amylose."

U.S. Patent No. 5,571,545 explains at col. 3, lines 14-18 that:

> "**alpha-starch** is obtained by gelatinizing starch obtained from starch containing raw materials such as cereals, rootcrops and the like and is used in an amount of 0.2 to 9% by weight, preferably 0.5 to 7.5% by weight as dry weight based on the total weight of the food material of the present invention."

The above patents add to the ample demonstration that the term "alpha-starch" is used as a generic and art-recognized term and is in fact used in patent claims. Applicants respectfully assert that this is probative evidence that the term is accepted in the art and capable of serving as a claim term. The Examiner in fact appreciated this evidence and stated during the February 25, 2003 interview that the claims were free of prior art.

During the interview, Applicants also again pointed out to the Examiner that over 173 patents had issued that used the term "alpha-starch" (see Attachment A). The Examiner's response to this was that she had no control over what other Examiners were doing. Applicants' respectfully asserted and repeat herein that the multitude of patents is indicative that the term is acceptable as a claim term, and does not constitute a prior Examiner's "mistake."

In sum, "alpha-starch" is a different material from unmodified starch, such as tapioca or other vegetable or root starches. In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, 1st ¶ are respectfully requested.

Applicants Remarks in Response to the Art Rejections:

The present invention relates to a water-decomposable material for treating excretions from animals, such as cats, dogs, pigs, rats, and the like. The invention is characterized by the use of "alpha-starch that readily dissolves in water and becomes sticky when brought into contact with water."

JP 11-032608 to *Sasahara* relates to a treating material that comprises a flat granular body have a two-layered structure which comprises a flat core material comprising hydro fillet organic fibers and a layer comprising water-absorbing polymer powder and organic fiber power covering the entire surface of the core material in an approximately constant thickness. According to this reference, a surfactant (a material very different from a starch derivative) may be added to the flat core material that comprises the hydro fillet organic fibers (see *Abs.*) However, this reference fails to disclose the alpha-starch as a component of an animal excretion treating material, as set forth in independent claim 1. Hence, there is no anticipation.

U.S. Patent No. 5,209,185 to *Chikazawa* relates to an artificial litter material that was applied allegedly to supplement the disclosure of the primary reference. This reference fails to cure the deficiency of the *Sasahara* reference. Specifically, *Chikazawa* fails to disclose the use of alpha-starch as a component of an animal excretion treating material, as set forth and claimed in the present invention. Tapioca is a native starch, not a physically modified starch.

No reference discloses or suggests that alpha-starch can be used to improve the ability of animal excretions-treating material to be disposed of in flush toilets.

Dependent claims 2-9 are directed to features that improve the ability of the animal excretions-treating material to be disposed of in flush toilets, and are patentable over the prior art for the same reasons discussed above with respect to claim 1.

In view of the foregoing remarks, the application is respectfully submitted to be in condition for allowance and prompt, favorable action thereon is earnestly solicited. However, should the Examiner believe that direct contact with Applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

Dated: April 11, 2003

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COMPLETE SET OF PENDING CLAIMS

1. An animal excretions treating material comprises particles, each particle being composed of a core layer of fibers and a skin layer to cover the core layer, the skin layer containing ∝-starch and fibers.

2. (Amended) The animal excretions treating material as set forth in claim 1, wherein the fibers constituting the skin layer are short fibers having a mean fiber length in a range of 0.02 to 1 mm.

3. The animal excretions treating material as set forth in claim 1, wherein the mean particle size of the ∝-starch in the skin layer is at most 0.25 mm.

4. (Amended) The animal excretions treating material as set forth in claim 1, wherein the composition of the skin layer is in a ratio of a starch to fibers in a range of 20 to 80 and 80 to 20.

5. The animal excretions treating material as set forth in claim 1, wherein the fibers in the skin layer are those of pulp.

6. The animal excretions treating material as set forth in claim 1, wherein the ∝-starch in the skin layer is tapioca a starch.

7. The animal excretions treating material as set forth in claim 1, wherein the fibers in the core layer are those of pulp.

8. (Amended) The animal excretions treating material as set forth in claim 1, which has a bulk density in a range of 0.1 and 0.5 g/cm^3.

9. (Amended) The animal excretions treating material as set forth in claim 1, the particle has a diameter in a range of 2 and 20 mm.

A